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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/555,971

11/14/2000

Ivo Glynne Gut

147-201P

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04/05/2004

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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/555,971

Applicant(s)

GUT ET AL.

Examiner

Frank W Lu

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 06 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's response to the office action filed on October 6, 2003 has been entered. The claims pending in this application are claims 1-20 wherein claims 11-13 have been withdrawn due to species election. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the amendment filed on October 6, 2003.

### ***Information Disclosure Statement***

2. The examiner notes that the specification (pages 19-21) has listing of references. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Note that applicant does not address this issue in the response filed on October 6, 2003.

### ***Specification***

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. For example, see description for Figure 4 in page 14 (see amendment filed on October 6, 2003). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Claim Objections***

4. Claim 1 is objected to because of the following informality: “probles” should be “probes”.
5. Claim 3 is objected to because of the following informality: there should be a word “or” before the phrase “via a protein-protein interaction”.
6. Claim 5 is objected to because of the following informality: “Gene32” should be “Gene32 protein”.
7. Claim 20 is objected to because of the following informality: “step (c)” in step (e) should be “step (d)”.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-10, 14-17, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
10. Claims 1 and 19 are rejected as vague and indefinite. From the step (e) of the claims, it is unclear how step (e) of the claims are related to steps (c) and (d) of the claims since step (e) of the claims only requires “by means of the probes hybridized to the nucleotide sequence”. Please clarify.

Art Unit: 1634

11. Claim 14 recites the limitation “randomized nucleotides” in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no “randomized nucleotides” in claims 1 and 9.
12. Claim 18 is rejected as vague and indefinite in view of the phrase “a probe support which has been pretreated and thus allows for the attachment of target DNAs and/or target DNAs that have already been attached” since, from this phrase, it is unclear whether target DNAs are on the a probe support or not. Please clarify.
13. Claim 20 is rejected as vague and indefinite. From the step (f) of the claim, it is unclear how step (f) of the claim is related to steps (d) and (e) of the claim since step (e) of the claim only requires “by means of the probes hybridized to the nucleotide sequence”. Please clarify.

***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1-3, 6-10, 16, 17, 19, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Ness *et al.*, (US Patent No. 6,613,508 B1, filed on July 22, 1997).

Ness *et al.*, teach methods and compositions for analyzing nucleic acid molecules utilizing sizing techniques.

Regarding claim 1, Ness *et al.*, teach a method for genotyping a selected organism, comprising the steps of (a) combining tagged nucleic acid molecules with a selected target molecule under conditions and for a time sufficient to permit hybridization of the tagged molecules to the target molecule, wherein a tag is correlative with a particular fragment and is detected by non-fluorescent spectrometry or potentiometry, (b) separating the tagged fragments by sequential length, (c) cleaving the tag from the tagged fragment, and (d) detecting the tag by non-fluorescent spectrometry or potentiometry, and therefrom determining the genotype of the organism (see columns 2-4 and 54). Since Ness *et al.*, teach combining tagged nucleic acid molecules with a selected target molecule under conditions and for a time sufficient to permit hybridization of the tagged molecules to the target molecule and separating the tagged nucleic acid molecules by sequential length (see columns 2, 3, and 54), the tagged nucleic acid molecules taught by Ness *et al.*, are with different mass. Therefore, Ness *et al.*, disclose hybridization of nucleic acid molecules to a set of probes of different nucleobase sequences, wherein each probe has a mass that differs from the one of all the other probes as recited in step (a) of claim 1. Since Ness *et al.*, teach separating the tagged nucleic acid molecules by sequential length or separating the target molecules, hybridized tagged probes, unhybridized probes or target molecules, probe:target hybrids, or tagged nucleic acid probes or molecules from other molecules utilizing methods which discriminate between the size of molecules such as HPLC or size exclusion chromatography (see columns 2-4 and 54) and it is known that HPLC or size exclusion chromatography is performed in a solvent, Ness *et al.*, disclose separation of the probes that are not hybridized and detachment of the probes that are hybridized in a solvent as recited in steps (b) and (c) of claim 1. Since Ness *et al.*, teach cleaving the tag from the

Art Unit: 1634

separated tagged nucleic acid molecule and detecting the tag by non-fluorescent spectrometry or potentiometry (see columns 2-4 and 54) such as electrospray ionization mass spectrometry (see column 3, last paragraph), Ness *et al.*, disclose analysis of the probes that are detached from step (c) by means of electrospray mass spectrometry as recited in step (d) of claim 1. Since, as shown above, Ness *et al.*, teach steps (a) to (d) for genotyping a selected organism, Ness *et al.*, disclose detecting the nucleotide sequence in the nucleic acid molecules by means of the probes hybridized to the nucleotide sequence as recited in step (e) of claim 1.

Regarding claim 2, Ness *et al.*, teach that the nucleic acid molecules (ie., a DNA population which is covalently immobilized to the solid support and generated from mRNA) are immobilized at a surface of a support before step (a) as recited in claim 2 (see column 54, lines 30-67).

Regarding claim 3, since Ness *et al.*, teach that the amines on the polymers of the solid support (ie., glass surface) are used to covalently immobilize oligonucleotides (see column 55, lines 9-67) and it is known that glass surface is a surface of the supports with a silicate or silane, Ness *et al.*, disclose that the immobilization of the nucleic acid molecules at the surface is carried out via  $\text{NH}_2$  as recited in claim 3.

Regarding claims 6-8, since Ness *et al.*, teach that each of nucleic acid probes is labeled with a cleavable mass spectrometry tag (see column 54, lines 30-67) wherein the tag carries a positive or negative charge (see column 16, lines 20-60), Ness *et al.*, disclose that the probes are nucleic acids having a mass tag as recited in claim 6, the mass tag is also a charge tag as recited in claim 7, and the nucleic acids have a charge tag as recited in claim 8.

Regarding claims 9 and 10, since nucleic acid defined by Ness *et al.*, can be a nucleic acid analog such as PNA (see column 10, last paragraph), Ness *et al.*, disclose that the probes are modified nucleic acid molecules wherein the modified nucleic acid molecules are PNAS as recited in claims 9 and 10.

Regarding claim 16, since the tagged nucleic acid molecules are more than one probe that are from an oligonucleotide combinatorial library generated by combinatorial chemistry (see columns 29 and 30) and each probe has a mass that differs from the one of all the other probes (see above rejection on claim 1), Ness *et al.*, disclose the probes are generated as partial libraries having different mass as recited in claim 16.

Regarding claim 17, since, after step (a) of claim 1, hybridized probes are indirectly immobilized on the surface of the support (see column 54, lines 30-67), Ness *et al.*, disclose that the positions of the probes on the support allow for an allocation to the nucleic acid molecules hybridizing thereto as recited in claim 17.

Regarding claim 19, Ness *et al.*, teach a method for genotyping a selected organism, comprising the steps of (a) combining tagged nucleic acid molecules with a selected target molecule under conditions and for a time sufficient to permit hybridization of the tagged molecules to the target molecule, wherein a tag is correlative with a particular fragment and is detected by non-fluorescent spectrometry or potentiometry, (b) separating the tagged fragments by sequential length, (c) cleaving the tag from the tagged fragment, and (d) detecting the tag by non-fluorescent spectrometry or potentiometry, and therefrom determining the genotype of the organism (see columns 2-4 and 54). Since Ness *et al.*, teach combining tagged nucleic acid molecules with a selected target molecule under conditions and for a time sufficient to permit



Art Unit: 1634

hybridization of the tagged molecules to the target molecule and separating the tagged nucleic acid molecules by sequential length (see columns 2, 3, and 54) and the tagged nucleic acid molecules are more than one probe that are from an oligonucleotide combinatorial library generated by combinatorial chemistry (see columns 29 and 30), the tagged nucleic acid molecules taught by Ness *et al.*, are partial libraries having different mass. Therefore, Ness *et al.*, disclose hybridization of nucleic acid molecules to a set of probes of different nucleobase sequences, wherein each probe has a mass that differs from the one of all the other probes and wherein the probes are generated as partial libraries having different mass as recited in step (a) of claim 19. Since Ness *et al.*, teach separating the tagged nucleic acid molecules by sequential length or separating the target molecules, hybridized tagged probes, unhybridized probes or target molecules, probe:target hybrids, or tagged nucleic acid probes or molecules from other molecules utilizing methods which discriminate between the size of molecules such as HPLC or size exclusion chromatography (see columns 2-4 and 54) and it is known that HPLC or size exclusion chromatography is performed in a solvent, Ness *et al.*, disclose separation of the probes that are not hybridized and detachment of the probes that are hybridized in a solvent as recited in steps (b) and (c) of claim 19. Since Ness *et al.*, teach cleaving the tag from the separated tagged nucleic acid molecule and detecting the tag by non-fluorescent spectrometry or potentiometry (see columns 2-4 and 54) such as electrospray ionization mass spectrometry (see column 3, last paragraph), Ness *et al.*, disclose analysis of the probes that are detached from step (c) by means of electrospray mass spectrometry as recited in step (d) of claim 19. Since, as shown above, Ness *et al.*, teach steps (a) to (d), Ness *et al.*, disclose detecting the nucleotide

Art Unit: 1634

sequence in the nucleic acid molecules by means of the probes hybridized to the nucleotide sequence as recited in step (e) of claim 19.

Regarding claim 20, Ness *et al.*, teach a method for genotyping a selected organism, comprising the steps of (a) combining tagged nucleic acid molecules with a selected target molecule under conditions and for a time sufficient to permit hybridization of the tagged molecules to the target molecule, wherein a tag is correlative with a particular fragment and is detected by non-fluorescent spectrometry or potentiometry, (b) separating the tagged fragments by sequential length, (c) cleaving the tag from the tagged fragment, and (d) detecting the tag by non-fluorescent spectrometry or potentiometry, and therefrom determining the genotype of the organism (see columns 2-4 and 54). Since Ness *et al.*, teach combining tagged nucleic acid molecules with a selected target molecule under conditions and for a time sufficient to permit hybridization of the tagged molecules to the target molecule and separating the tagged nucleic acid molecules by sequential length (see columns 2, 3, and 54), the tagged nucleic acid molecules taught by Ness *et al.*, are with different mass. Therefore, Ness *et al.*, disclose hybridization of nucleic acid molecules to a set of probes of different nucleobase sequences, wherein each probe has a mass that differs from the one of all the other probes as recited in step (a) of claim 20. Since Ness *et al.*, teach that the nucleic acid molecules (ie., a DNA population which is covalently immobilized to the solid support and generated from mRNA) are immobilized at a surface of a support before step (a) (see column 54, lines 30-67) wherein the amines on the polymers of the solid support (ie., glass surface) are used to covalently immobilize oligonucleotides (see column 55, lines 9-67), and it is known that glass surface is a surface of the supports with a silicate or silane, Ness *et al.*, disclose the immobilization of the nucleic acid

Art Unit: 1634

molecules at the surface is carried out via NH<sub>2</sub> as recited in step (b) of claim 20. Since Ness *et al.*, teach separating the tagged nucleic acid molecules by sequential length or separating the target molecules, hybridized tagged probes, unhybridized probes or target molecules, probe:target hybrids, or tagged nucleic acid probes or molecules from other molecules utilizing methods which discriminate between the size of molecules such as HPLC or size exclusion chromatography (see columns 2-4 and 54) and it is known that HPLC or size exclusion chromatography is performed in a solvent, Ness *et al.*, disclose separation of the probes that are not hybridized and detachment of the probes that are hybridized in a solvent as recited in steps (c) and (d) of claim 20. Since Ness *et al.*, teach cleaving the tag from the separated tagged nucleic acid molecule, and detecting the tag by non-fluorescent spectrometry or potentiometry (see columns 2-4 and 54) such as electrospray ionization mass spectrometry (see column 3, last paragraph), Ness *et al.*, disclose analysis of the probes that are detached from step (d) by means of electrospray mass spectrometry as recited in step (e) of claim 20. Since, as shown above, Ness *et al.*, teach steps (a) to (e) for genotyping a selected organism, Ness *et al.*, disclose detecting the nucleotide sequence in the nucleic acid molecules by means of the probes hybridized to the nucleotide sequence as recited in step (f) of claim 20. .

Therefore, Ness *et al.*, teach all limitation recited in claims 1-3, 6-10, 16, 17, 19, and 20.

### ***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1634

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ness *et al.*, (1997) as applied to claims 1-3, 6-10, 16, 17, 19, and 20 above, and further in view of Shuber (US Patent No. 5,888,778, filed on June 16, 1997).

The teachings of Ness *et al.*, have been summarized previously, *supra*.

Ness *et al.*, do not disclose that the protein-substrate interaction is by means of an antibody-antigen bond as recited in claim 4.

Shuber teaches that antibodies is used to attach target nucleic acids to a solid support by coating the surfaces of the support with the antibodies and incorporating an antibody-specific hapten into the target nucleic acids. Alternatively, the target nucleic acids are attached directly to a solid support by epoxide/amine coupling chemistry (see column 11, second paragraph).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have immobilized the nucleic acid molecules recited in claim 1 by means of an antibody-antigen bond in view of the patents of Ness *et al.*, and Shuber. One having ordinary skill in the art would have been motivated to do so because Shuber has

Art Unit: 1634

successfully attached target nucleic acids to a solid support by coating the surfaces of the support with the antibodies and incorporating an antibody-specific hapten into the target nucleic acids and the simple replacement of one well known immobilization method (i.e., amine coupling chemistry taught by Ness *et al.*,) from another well known immobilization method (i.e., antibody-antigen bond taught by Shuber) during the process of performing the method recited in claim 1 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made because immobilization by amine coupling taught by Ness *et al.*, and immobilization by antibody-antigen bond taught by Shuber are two functional equivalent methods for nucleic acid immobilization which are used for the same purpose and two methods are exchangeable (see Shuber, column 11).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06.

18. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ness *et al.*, (1997) further in view of Shuber (US Patent No. 5,888,778, filed on June 16, 1997) applied to claims 1-4, 6-10, 16, 17, 19, and 20 above, and further in view of Cros *et al.*, (US Patent No. 5,849, 480, 102 (e) date: March 16, 1995).

The teachings of Ness *et al.*, and Shuber have been summarized previously, *supra*.

Ness *et al.*, and Shuber do not disclose that the protein-nucleic acid interaction is by

Art Unit: 1634

means of a Gene32-nucleic acid bond as recited in claim 5.

Cros *et al.*, teach to attach a nucleic acid fragment-hapten conjugate onto the solid support by interacting with an anti-conjugate compound such as Gene32 protein coated on the support. The anti-conjugate compound can be an anti-nucleic acid fragment antibody (see column 5, lines 7-39).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have immobilized the nucleic acid molecules recited in claim 1 by means of a Gene-32 protein-nucleic acid bond in view of the patents of Ness *et al.*, and Cros *et al.*. One having ordinary skill in the art would have been motivated to do so because Cros *et al.*, has successfully attached a nucleic acid fragment-hapten conjugate onto the solid support by interacting with an anti-conjugate compound (i.e., Gene32 protein) coated on the support and Gene32 protein coated on the support would reduce non-specific binding of the nucleic acid fragment to the support because this protein only binds to single stranded nucleic acids (see column 5, lines 21-39), and the simple replacement of one known immobilization method (i.e., anti-nucleic acid fragment antibody-nucleic acid bond taught by Shuber) from another well known immobilization method (i.e., Gene-32 protein-nucleic acid bond taught by Cros *et al.*,) during the process of performing the method recited in claim 1 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made because immobilization of the nucleic acid by anti-nucleic acid fragment antibody-nucleic acid bond taught by Shuber and immobilization of the nucleic acid by Gene-32 protein-nucleic acid bond taught by Cros *et al.*, are two functional equivalent methods which are used for the same purpose, and both anti-nucleic acid fragment

Art Unit: 1634

antibody and Gene-32 protein are anti-conjugate compound and are exchangeable (see Cros *et al.*, column 5, lines 21-39).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06.

19. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ness *et al.*, as applied to claims 1-3, 6-10, 16, 17, 19, and 20 in view of Stratagene catalog (page 39, 1998).

The teachings of Ness *et al.*, have been summarized previously, *supra*.

Regarding claim 18, since, as shown the rejection under 35 U.S.C 102, Ness *et al.*, teach claim 6, Ness *et al.*, disclose a set of probes as defined in claim 6 as recited in (a) of claim 18. Since Ness *et al.*, teach a solid support coated with an amine-polymer wherein the amines on the polymer are used to covalently immobilize oligonucleotides (see column 55, lines 9-67), Ness *et al.*, disclose a probe support which has been pretreated and thus allows for the attachment of target DNAs as recited in (b) of claim 18.

Ness *et al.*, also teach a kit comprising a plurality of amplification primer pairs (see column 41, lines 61-67 and column 42, lines 1-13).

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine a set of probes and a probe support taught by Ness *et al.*, into a kit format as discussed by Stratagene catalog since the Stratagene catalog

Art Unit: 1634

teaches a motivation for combining reagents of use in an assay into a kit, “[E]ach kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. 2) The other service provided in a kit is quality control” (page 39, column 1).

### *Response to Arguments*

20. Applicant's arguments with respect to claims 1-10 and 14-20 have been considered but are moot in view of the new ground(s) of rejection.

### *Conclusion*

21. No claim is allowed.

22. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.



Art Unit: 1634

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu  
PSA  
March 18, 2004

  
**FRANK LU**  
**PATENT EXAMINER**